

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

REMARKS

Claims 16 and 19 were objected to due to an informality. The claims have been amended above to address the examiner's concerns.

Claims 5 and 15 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The examiner is requested to reconsider this rejection.

Applicants' claimed invention is directed to measuring edema of skin layers and subcutaneous fat tissue.

The examiner is first directed to page 3, lines 12-16, of the present application which states:

"An essential feature of the invention is the high radio frequency (approximately 20-500 MHz), because at these frequencies the electric field penetrates deeply into the skin and subcutaneous fat tissue. At lower frequencies the electric field is concentrated on the superficial layers of the skin and the measurement of edema is not possible". [emphasis added]

Additionally, page 4, lines 1-9 further states that:

"In a further advantageous application of the invention the edema is measured from the upper layers of the skin by using 20-50 MHz radio frequencies, in which case the electric field is concentrated on these layers. In this way the upper layers of the skin can be measured without any delay and reliably". [emphasis added]

Appl. No.: 10/670,144  
Reply to Office Action of 04/12/2011

"In a further advantageous application of the invention the edema is measured from deeper layers of the skin by using 50-500 MHz radio frequencies, in which case the electric field penetrates deeply into the skin tissue (dermis) and the underlying subcutaneous fat tissue. In this way the deeper layers of the skin and the underlying fat tissue can be measured without any delay and reliably". [emphasis added]

Applicants have amended claim 5 to address the examiner's concerns. Claim 5 now claims "the edema of upper layers of the skin is measured using a frequency of approximately 20-50 MHz, in which case an electric field is concentrated in the upper layers of the skin".

Applicants submit that the specification describes the invention with sufficient detail to support the invention as claimed.

For example, the recitation in claim 5 is supported by the specification at page 4, lines 1-9 (as shown above). The previously recited "uppermost layers of the skin" was included to reference the uppermost layers of the skin below the superficial layers of the skin, or in other words, to reference the uppermost layers of the dermis (i.e. below the epidermis). However, to expedite prosecution and to address the examiner's concerns, applicants have amended claim 5 to recite "upper layers of the skin".

Claim 15 recites "wherein the measuring of the capacitance of the probe at the high frequency further comprises measuring the edema at layers of the skin beyond superficial layers of

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

the skin". The 'superficial layers' are the outermost layers of the skin (such as at the epidermis). Therefore, in applicants claimed invention, 'measuring beyond superficial layers' means measuring upper layers of the skin (below the superficial layers, since it is stated a page 3, lines 12-16, that "measurement of edema is not possible"), measuring deeper layers of the skin, dermis, etc.

Applicants therefore submit that the specification supports the claimed features. The invention "as claimed" is fully described in such a way to enable a person skilled in the art to make and/or use the invention. The examiner is requested to reconsider his §112, first paragraph rejections.

Claims 1-8, and 12-19 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The claims have been amended above to address the examiner's concerns. In particular, claims 1 and 7 have been amended to recite "the electric field to penetrate past the skin ...". Additionally, claim 7 has been amended to address the 'measured value' and 'electrodes' recitation.

Claims 1-8, and 12-19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112, second paragraph, and claim objections. As detailed above, claims 1 and 7 have been amended to address the examiner's concerns and overcome the rejections under 35 U.S.C. §112, second paragraph. Therefore, in view of section 16 of the Office Action, claims 1-8 and 12-19 should now be in condition for allowance.

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Malicki et al. (US 4,918,375) in view of Campbell et al. (US 2003/0015024) and Measurement of Dielectric Properties of Subcutaneous Fat with Open-Ended Coaxial Sensors by Esko et al. ("Measurement"). The examiner is requested to reconsider this rejection.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicants have amended claim 11 to recite, *inter alia*, "detecting edema based on, at least partially, the water content".

Malicki et al. discloses a reflectrometric moisture meter for capillary-porous materials, especially for the soil. The measuring is made by using oblong dagger-like electrodes inserted into the soil (see col. 2, lines 11-12). As mentioned in the title of the patent, this meter is for the measuring of soil. There is no mention or description of measuring of the edema or measuring the skin. Applicants further submit that skin is not a capillary-porous material as described in patent of Malicki. In particular, Malicki teaches that the meter "can be applied for any such capillary-porous material which allows introduction of the probe in a non-destructive way .. [s]uch materials include: the soil, agricultural products (grain, hop cones, tobacco leaves, hay), food industry products (flour, bakery products), wood, moulding sand, subgrades, building foundations etc".

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

Campbell fails to provide a teaching directed to measuring edema. Campbell does not disclose a device to measure tissue water content. Instead, Campbell teaches measuring skin surface hydration. Furthermore, there is no disclosure or suggestion of the capacitance of the probe as proportional to dielectric constant and water content of the skin. Additionally, the examiner admits that Campbell is silent as to the frequency used and the distance between the two electrodes of the probe.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. Additionally, the article Measurement does not disclose that a measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is clear difference when comparing to the current application where is no reference to use different size of the probes at the same time. Furthermore, there is no mention in the article that these measurements are used to detect edema.

The article "Penetration" is directed to describing how the choice of measuring frequency affects on the measuring depth. The result is that at high frequencies (above 100 MHz) the open-ended coaxial probe measures the skin and subcutaneous tissue, and at lower frequencies (below 10 MHz) it measures

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

mainly the superficial structures [see Conclusion, first paragraph, last sentence, p N174]. There is no mention in the article that the method presented would be used to measure tissue edema.

Neither Malicki, Campbell, Measurement, nor Penetration teach or suggest anything relating to measuring edema.

Applicants further submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). For example, Malicki teaches that the oblong dagger-like electrodes 1a, 1b, 1c, have lengths of 0.1 m, 0.25 m, and 0.5 m (see col. 6, lines 64-68). These large electrodes are inserted into the soil and each spaced several meters from each other (see Fig. 1). There is no disclosure or suggestion in Malicki of inserting the oblong dagger-like electrodes into the skin of a person. Thus, it is clear that the teachings of Malicki are directed to industrial applications. Whereas, the teachings of Campbell, Measurement, and Penetration are directed to measurements on human skin.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. (see MPEP 2143.01, page 2100-98, column 1). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (see

Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

MPEP 2143.01, page 2100-98, column 2). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. (see MPEP 2143.01, page 2100-99, column 1) Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). >See also Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.)

In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide a method for measuring tissue edema comprising detecting edema based on, at least partially, the water content, as claimed in claim 11. The features of claim 11 are not disclosed or suggested in the art of record. Therefore, claim 11 is patentable and should be allowed.

Claims 20 and 21 have been added above to further claim the features recited therein.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record. Accordingly, favorable reconsideration and allowance is respectfully requested. If there are any additional charges

JUL. 11. 2011 12:47PM

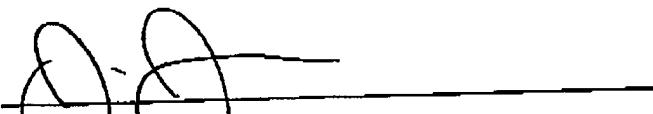
HARRINGTON & SMITH

NO. 293 P. 15

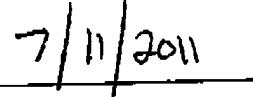
Appl. No.: 10/670,144  
Reply to Office Action of: 04/12/2011

with respect to this Amendment or otherwise, please charge deposit account 50-1924 for any fee deficiency. Should any unresolved issue remain, the examiner is invited to call applicants' attorney at the telephone number indicated below.

Respectfully submitted,



Juan Juan (Reg. No. 60,564)

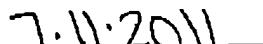


Date

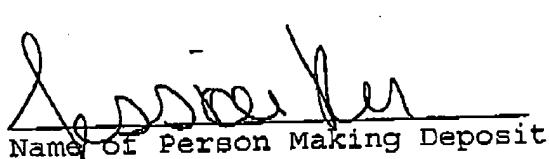
Customer No.: 29683  
Harrington & Smith,  
Attorneys At Law, LLC  
4 Research Drive  
Shelton, CT 06484-6212  
203-925-9400

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.



Date



Name of Person Making Deposit